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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/775,034	02/09/2004	Stephanie M. Kladakis	022956-0260	6915

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EXAMINER

PELLEGRINO, BRIAN E

ART UNIT	PAPER NUMBER
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3738

NOTIFICATION DATE	DELIVERY MODE
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11/30/2007

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docket@nutter.com

Office Action Summary

Application No.

10/775,034

Applicant(s)

DEPUY MITEK INC.

Examiner

Brian E. Pellegrino

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 September 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-6,9,10,13-18,20,21,24-28,30-39 and 42-53 is/are pending in the application.
- 4a) Of the above claim(s) 32 and 33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-6,9,10,13-18,20,21,24-28,30,31,34-39 and 42-53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>9/13/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/10/07 has been entered.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1,3-6,9,10,13-18,20,21,24-28,30,31,34-39,42-44,46-50,52,53 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Schwartz et al. (2003/78617). Fig. 17 shows a wedge-shaped tissue scaffold. Schwartz et al. disclose the tissue repair device comprises a porous resorbable material, paragraphs 16,17. Schwartz also discloses the material can be synthetic, paragraphs 83,86,94. It can be seen the implant includes top and bottom portions **24,26** respectively. Fig. 34 illustrates the top and bottom portions can be mated to one another. Schwartz discloses the implant pocket material can be an ECM. Schwartz additionally shows (Fig. 23) that there is a tissue material **22** placed in a pocket or hollow interior or lumen that extends from the

greater height to the tapered smaller end and is formed between the top and bottom portions. Bioactive substances can be added to the tissue material, paragraphs 130,131. Schwartz et al. disclose that tissue is obtained and comminuted (i.e. mince, slice or sliver) to smaller fragments and then loaded between or within the pocket of the tissue scaffold, paragraphs 16,17,83. Schwartz et al. disclose that osteoblasts are one type of cells placed therein, paragraph 133. Budny (2005/147645) teaches that an ECM provides the necessary framework for cell migration, such as osteoblasts, paragraph 25. Thus, it is inherent that the cells of Schwartz's implantable device migrate into the scaffold. Figs. 26 and 31 show the implantation is done such that native tissue **12** abuts the opening of the pocket to maintain the tissue **22** therein. Regarding claims 42,43,46-49,52,53 since the ECM **21** covers a portion of the native tissue **12** (Fig. 19) it can be construed that the cells populate a portion of the scaffold and cells from the native tissue populate a portion of the scaffold that lie beneath that portion of the scaffold. With respect to claims 44,50 Schwartz discloses the size of the fragment or tissue can be about 200µm, paragraph 122.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 45,51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwartz et al. (2003/78617). Schwartz et al. is explained supra. It is noted that Schwartz does disclose that the particle size can be any dimension and is not to be limited to particular dimensions, paragraph 122. However, Schwartz fails to explicitly disclose the tissue fragments are of a particle size having the dimension of 0.5 mm^3 to 3 mm^3 . It would have been obvious to one of ordinary skill in the art to utilize a particle dimension as claimed since such a modification only involves routine skill in the art and varying the size would not affect the function of the cells.

Response to Arguments

Applicant's arguments filed 9/10/07 have been fully considered but they are not persuasive. Applicant argues that the cells disclosed by Schwartz are not capable of migrating into the scaffold. It is well known in the tissue regeneration art that cells used in tissue repair are capable of migrating. It is also known in the art that tissue scaffolds or ECM material fully supports cell migration as stated in the Budny reference. The Applicant has not structurally differentiated how the scaffold of Schwartz is any different than the claimed invention. If the prior art structure is capable of performing the intended use, then it meets the claim. Thus, since Schwartz discloses a material capable of the intended use, the Examiner is not persuaded.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E. Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M-Fr (7:30am-4pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TC 3700, AU 3738

BRIAN E. PELLEGRINO
PRIMARY EXAMINER

Brian Pellegrino